Amendments to the Specification:

Please replace the paragraph beginning at page 1, lines 3-10, as with the following amended paragraph:

This application claims the benefit of priority under 35 U.S.C. §119(e) to U.S. provisional application Serial No. 60/446,288, filed February 6, 2003, U.S. provisional application Serial No. 60/466,526, filed April 28, 2003, and U.S. provisional application Serial No. 60/490,706, filed July 28, 2003. The subject matter and disclosure of ~~U.S. application Serial No. attorney dkt. no. 24727-826PC~~ International PCT Application Serial No. PCT/US2004/003428, which is filed on the same day herewith, and the subject matter and disclosures of each of the above-noted applications is incorporated herein by reference.

Please replace the paragraph beginning at page 2, line 24 to page 3, line 28, with the following amended paragraph:

Also provided herein are methods of screening and treating a subject where a body fluid sample, such as a sample of urine, blood, plasma, saliva, cervical fluid or vaginal fluid, is obtained from the subject and the level of fetal fibronectin therein is detected. In one embodiment, the subject is a subject at risk for preterm delivery. If the level of fetal fibronectin meets a predetermined selection criterion ~~indiciative~~ indicative of such risk or of imminent or preterm delivery, a therapeutically effective amount of a progestational agent is administered to the subject. In certain embodiments, the sample is obtained after about 12 weeks, after about 16 weeks, or after about 20 weeks gestation. In another embodiment, the progestational agent contains at least one omega-3 fatty acid, or derivative thereof, such as, for example, docosahexaenoic acid (DHA). In another embodiment, the progestational agent contains at least one progesterone or derivative thereof, such as, for example, 17-α-hydroxyprogesterone caproate. In a further embodiment, the therapeutically effective amount of the progestational agent is administered at of a dosage of at least about 100 mg/week, 250 mg/week, 500 mg/week, 1000 mg/week, 1500 mg/week, or 2000 mg/week of the progestational agent. Alternatively, the therapeutically effective amount of the progestational agent is ~~adminstered~~ administered at a dosage of at least about 10 mg/day, 25 mg/day, 80 mg/day, 100 mg/day, 200 mg/day, or 300 mg/day, or more, of the progestational agent. The progestational agent can be administered by any suitable route, including orally, by

intramuscular injection, transdermally, or intranasally. In yet another embodiment, the progestational agent is administered after the start of fetal organogenesis. Alternatively, the progestational agent is administered after about 12 weeks, after about 16 weeks, after about 20 weeks, after about 28 weeks, or after about 35 weeks gestation. The administration of the progestational agent can be stopped at about 36 weeks gestation or at the onset of spontaneous labor. In another embodiment, the predetermined selection criterion includes a threshold value, where the progestational agent is administered to the subject when the level of fetal fibronectin is above the threshold value (e.g., about 50 ng/mL). In still other embodiments, the level of fetal fibronectin is detected using an immunoassay, such as, but are not limited to, a homogeneous or heterogeneous, sandwich or competitive assay.

Please replace the paragraph beginning at page 7, lines 25-37, with the following amended paragraph:

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by one of skill in the art to which the inventions belong. All patents, patent applications, published applications and publications, Genbank sequences, websites and other published materials referred to throughout the entire disclosure herein, unless noted otherwise, are incorporated by reference in their entirety. In the event that there [[are]]is a plurality of definitions for terms herein, those in this section prevail. Where reference is made to a URL or other such identifier or address, it understood that such identifiers can change and particular information on the internet can come and go, but equivalent information is known and can be readily accessed, such as by searching the internet and/or appropriate databases. Reference thereto evidences the availability and public dissemination of such information.

Please replace the paragraph beginning at page 11, line 27 to page 12, line 25, with the following amended paragraph:

As used herein, a derivative of a compound includes a salt, ester, enol ether, enol ester, solvate or hydrate thereof that can be readily prepared by those of skill in this art using known methods for such derivatization. Salts include, but are not limited to, amine salts, such as but not limited to N,N'-dibenzylethylenediamine, chloroprocaine, choline, ammonia, diethanolamine and other hydroxyalkylamines, ethylenediamine, N-

methylglucamine, procaine, N-benzylphenethylamine, 1-para-chloro-benzyl-2-pyrrolidin-1'-ylmethylbenzimidazole, diethylamine and other alkylamines, piperazine and tris(hydroxymethyl)aminomethane; alkali metal salts, such as but not limited to lithium, potassium and sodium; alkali earth metal salts, such as but not limited to barium, calcium and magnesium; transition metal salts, such as but not limited to zinc; and other metal salts, such as but not limited to sodium hydrogen phosphate and disodium phosphate; and also including, but not limited to, salts of mineral acids, such as but not limited to hydrochlorides and sulfates; and salts of organic acids, such as but not limited to acetates, lactates, malates, tartrates, citrates, ascorbates, succinates, butyrates, valerates and fumarates. Esters include, but are not limited to, alkyl, alkenyl, alkynyl, aryl, heteroaryl, aralkyl, heteroaralkyl, cycloalkyl and heterocyclyl esters of acidic groups, including, but not limited to, carboxylic acids, phosphoric acids, phosphinic acids, sulfonic acids, sulfinic acids and boronic acids. Enol ethers include, but are not limited to, derivatives of formula C=C(OR) where R is hydrogen, alkyl, alkenyl, alkynyl, aryl, heteroaryl, aralkyl, heteroaralkyl, cycloalkyl [[ar]] and heterocyclyl. Enol esters include, but are not limited to, derivatives of formula C=C(OC(O)R) where R is hydrogen, alkyl, alkenyl, alkynyl, aryl, heteroaryl, aralkyl, heteroaralkyl, cycloalkyl [[ar]] and heterocyclyl. Solvates and hydrates are complexes of a compound with one or more solvent or water molecule, preferably 1 to about 100, more preferably 1 to about 10, most preferably one to about 2, 3 or 4, solvent or water molecules.

Please replace the paragraph beginning at page 13, lines 13-19, with the following amended paragraph:

As used herein, specific binding or selective binding means that [[a]] the binding of two compounds (k_a or K_{eq}) is at least 2-fold, generally, 5, 10, 50, 100 or more-fold, greater than for another receptor. A statement that a particular viral vector is targeted to a cell or tissue means that its affinity for such cell or tissue in a host or *in vitro* is at least about 2-fold, generally, 5, 10, 50, 100 or more-fold, greater than for other cells and tissues in the host or under the *in vitro* conditions.

Please replace the paragraph beginning at page 17, lines 10-14, with the following amended paragraph:

As used herein, a mobilizable antibody or fragment thereof refers to an antibody present on solid support such as a test strip, which, upon contact with a liquid, such as material from a sample, the antibody is not immobilized onto the solid support (*e.g.*, the antibody is ~~disolved~~ dissolved into the sample).

Please replace the paragraph beginning at page 19, lines 14-21, with the following amended paragraph:

A test sample which is to be assayed is removed in the vicinity of the posterior fornix, the cervical canal, the ectocervix and/or the external cervical os. The sample generally comprises fluid and particulate solids, and can contain vaginal or cervical mucus, other vaginal or cervical secretions, cells or cell debris, amniotic fluid, or other fetal or maternal materials. The sample can be removed using any of a variety of techniques including, but not limited to, use of a swab having a ~~dacron~~ DACRON or other fibrous tip, aspirator, suction device, lavage device or the like.

Please replace the paragraph beginning at page 27, lines 10-19, with the following amended paragraph:

Suitable antibody labels are well known to those of skill in the art. The labels include, but are not limited to colored labels, such as colored particles and colloidal metals, such as latex beads and colloidal gold; enzyme-substrate combinations that produce color (or ~~fluoroescence~~ fluorescence or other electromagnetic radiation) upon reaction. Colored particles, such as latex particles, colloidal metal or metal or carbon sol labels, fluorescent labels, and liposome or polymer sacs, are detected due to aggregation of the label. In one particular embodiment, the antibody is labelled with a colored latex particle. In an alternative embodiment, colloidal gold is used in the labeled antibody conjugate.

Please replace the paragraph beginning at page 28, lines 17-26, with the following amended paragraph:

Methods for measuring fetal fibronectin and cellular fibronectin levels in cervicovaginal samples are known in the art (see, *e.g.*, U.S. Patent Nos. 5,096,830, 5,185,270, 5,223,440, 5,236,846, 5,281,522, 5,468,619 and 5,516,702), and diagnostic tests for various pregnancy-related disorders are known in the art (see, *e.g.*, U.S. Patent Nos. 5,096,830, 5,079,171). These methods can be adapted for use with known immunoassay test strips and

devices for measuring fetal ~~fibronecin~~ fibronectin and, if desired, cellular fibronectin. Such ~~measurments~~ measurements are exemplified in U.S. Patent No. 6,267,722. In particular, an immunoassay test strip for measuring fFN in cervicovaginal samples is provided therein.

Please replace the paragraph beginning at page 29, lines 19-29, with the following amended paragraph:

In conducting the assay, a subject sample is obtained. The sample can include fluid and particulate solids, and, thus, can be filtered prior to application to the assay test strip. The sample can be removed from the subject using a swab having a fibrous tip, an aspirator, suction or lavage device, syringe, or any other known method of removing a bodily sample, including passive methods for collecting urine or saliva. In particular, the sample can be extracted into a buffer solution, and optionally heated, for example, at 37°C and filtered. In one embodiment, where fetal fibronectin is to be detected in a sample, the sample is obtained from in the vicinity of the posterior fornix, the ectocervix or external cervical os using a swab having a ~~dacron~~ DACRON or other fibrous tip.

Please replace the paragraph beginning at page 32, line 23 to page 33, line 3, with the following amended paragraph:

Assays are generally directed to detection of unconjugated or free estriol, since conjugated estriol has reduced biological activity. In saliva about 92% of estriol is in the free form, while most estriol in urine is present as a conjugate. As will be clear to those familiar with steroid metabolism, an estriol conjugate is a compound formed by formation of a covalent linkage of a non-steroidal compound to estriol. Linkage is typically through a hydroxyl group of the steroidal ring system. The non-steroidal component can be inorganic (*e.g.*, a sulfate group) or organic (*e.g.*, a glucuronide group). Methods that include determining the ratio of estriol/progesterone can also be determined on the basis of unconjugated estriol/progesterone ~~raitios~~,ratios and therefore can include unconjugated estriol measurements using saliva samples.

Please replace the paragraph beginning at page 34, lines 8-25, with the following amended paragraph:

The first general standard set out above, namely a predetermined range of estriol concentrations for the same body fluid in normal pregnant humans in general, is

typically obtained by using the same assay technique that will be used in the application of the method to an individual being tested, in order to ensure the highest correlation. Sufficient measurements are made in a normal population of pregnant women to produce a statistically significant range of normal values for the value to which a comparison will be made, which typically is at preselected time intervals during normal pregnancy. While comparison to a time immediately prior to normal delivery (38 to 40 weeks) is often used, other time periods can be used. For example, estriol levels during a given week of [[a]]an individual pregnancy (*i.e.*, that of the subject ~~subject~~) can be compared to the normal range of concentrations for the same time period (*e.g.*, the 20th week). Generally, the minimum concentration indicative of possible onset of labor is considered to be at least 1, generally at least 2, typically at least 3 or at least 4, standard deviations above the mean estriol concentration determined just prior to the onset of labor for normal pregnant humans for any given body fluid.

Please replace the paragraph beginning at page 41, lines 22-31, with the following amended paragraph:

Preparation of immunogenic compositions of IGFBP-1 can vary depending on the host animal and is well known. For example, IGFBP-1 or an antigenic portion thereof can be conjugated to an immunogenic substance such as KLH or BSA, or provided in an adjuvant or the like. The induced antibodies can be tested to determine whether the composition is IGFBP-1-specific. If a polyclonal antibody composition does not provide the desired specificity, the antibodies can be purified to enhance specificity by a variety of conventional methods. For example, the composition can be purified to reduce binding to other substances by contacting the composition with IGFBP-1 affixed to a solid substrate. Those antibodies which bind to the substrate are retained. Purification techniques using antigens affixed to a variety of solid substrates such as affinity chromatography materials including ~~Sephadex, Sepharose~~ SEPHADEX, SEPHAROSE and the like are well known.

Please replace the paragraph beginning at page 46, lines 3-17, with the following amended paragraph:

Kits are packaged combinations that optionally include instructions and/or other reagents or devices. A kit can include a device for obtaining a sample from the subject. For example, the kit can contain a vaginal sample collection device such as a ~~dacron~~ DACRON swab, a vaginal sample filtration device, and/or a vessel containing a vaginal sample diluent. In another example, the kit can contain a saliva sample collection device. Kits can also include one or more reagents such as buffers for stabilizing the sample and/or reagents for detecting the presence of an anti-(preterm delivery marker) antibody. Kits can include filters or compositions that remove background material and/or enhance detection of a preterm delivery marker. The combinations and kits optionally including instructions for collecting the sample and/or performing the assay. A variety of combinations and kits are known in the art which can be adapted for use in the methods provided herein. Such known kits are exemplified in U.S. Patent Nos. 5,281,522, 6,394,952, and 6,267,722.

Please replace the paragraph beginning at page 52, line 28 to page 53, line 9, with the following amended paragraph:

The assay was performed as follows. All samples were collected in the vicinity of the posterior fornix or cervical os using ~~dacron~~ DACRON swabs. Swab samples were immersed in 1.0 mL of sample diluent in a collection vial. The sample diluent solution is described above. The swabs were removed from the solution leaving as such liquid as possible in the collection tube. The samples were incubated at 37° C. along with the controls from the assay kit for 15 minutes prior to the assay, either before or after filtration. A sample filter was snapped in place on each sample tube. The 8-well strips were snapped into place in a strip holder. The holder had the alphanumeric indications of the 12 columns and eight rows of standard microtiter plates. Duplicate 100 μL aliquots of each sample and the positive and negative controls were placed in separate wells of the microtiter strip and incubated for 1 hour at room temperature.

Please replace the paragraph beginning at page 56, lines 10-23, with the following amended paragraph:

An assay kit for the fetal restricted antigen, fetal fibronectin included the following components. This kit was designed to be used to perform a rapid, bedside assay.

1. an assay device comprising a plastic housing and containing:
   (a) a porous nylon membrane to which is bound a monoclonal anti-fetal fibronectin antibody;
   (b) a flow control membrane system; and (c) an absorbent layer
2. a colloidal gold-labeled goat anti-fibronectin antibody conjugate in a protein matrix
3. conjugate reconstitution buffer
4. a wash solution
5. a sterile, ~~dacron~~ DACRON sample collection swab

Please replace the paragraph beginning at page 57, lines 24-30, with the following amended paragraph:

The stock conjugate was concentrated approximately 10- to 12-fold by ultrafiltration using a hollow fiber filter. The concentrated conjugate was diluted to an appropriate level in 15 mM Tris, 2% BSA, 0.1% ~~Tween 20,~~ TWEEN 20, 0.2% polyethylene glycol, 8% polyvinylpyrrolidine and 0.04% thimerosal. An appropriate concentration was determined by using a range of dilutions in a sample assay procedure as described below and determining the dilution which produces the best result.

Please replace the paragraph beginning at page 58, lines 10-11, with the following amended paragraph:

The kit additionally contains an individually packaged sterile ~~dacron~~ DACRON swab and a procedural summary card.

Please replace the paragraph beginning at page 61, lines 11-17, with the following amended paragraph:

Cervicovaginal secretion samples were prepared as described in Example 9. Duplicate 100 µl aliquots of each sample or a dilution thereof, and the positive and negative controls were placed in separate wells of the microtiter plate and incubated for 2 hours at room temperature. Following incubation, the wells were washed three times in rinse buffer (0.02 M Tris, pH 7.9, 0.15 M NaCl, 0.05% TWEEN-20, and 0.02% ~~sodiumazide).~~ sodium azide).

Please replace the paragraph beginning at page 62, lines 16-27, with the following amended paragraph:

The circulating levels of IGFBP-1 in maternal ~~plasmal~~ plasma were examined to determine if blood contamination of cervicovaginal secretions interfered with the test for IGFBP-1. The levels of IGFBP-1 in maternal plasma ranged from less than 10 ng/mL to 250 ng/mL and averaged about 150 ng/mL. Most of the rupture of membranes-positive cervicovaginal secretions specimens registered levels of IGFBP-1 of greater than 250 ng/mL. Thus, levels of IGFBP-1 in cervicovaginal secretions are a reliable indicator of rupture of membranes (ROM) in the presence of 10% blood or absence of blood in cervicovaginal secretion samples. Moreover, when fetal fibronectin is positive (> 50 ng/mL) the absence of IGFBP-1 is a reliable indicator that rupture of membranes has not occurred even though fetal fibronectin is present.